MAY 3 0 2001

K011027

510(K) SUMMARY

Submitted by:
Organogenesis Inc.
150 Dan Road
Canton, Massachusetts 02021

Contact
Patrick R. Bilbo
Telephone: (781) 401-1155
Facsimile: (781) 401-1109

Date: April 4, 2001

Device:

Trade Name:	FortaFlex™ Surgical Sling
Common/Usual Name:	Surgical Mesh, Sling, Tissue Support Biomaterial
Classification Name:	Surgical Mesh (79FTM, 21CFR 878.3300)
Regulatory Class:	Class II

Predicate Device:
The device is similar to predicate collagen-based surgical mesh and sling devices previously cleared for commercial distribution. The relevant predicate devices include GraftPatch™ (K970561) manufactured by Organogenesis Inc. and Surgisis™ Sling (K992159) manufactured by Cook Biotech, Incorporated.

Statement of Substantial Equivalence:
The FortaFlex Surgical Sling is substantially equivalent to the predicate devices, having similar intended use, technological characteristics, materials, physical construction and performance.

Intended Use:
FortaFlex™ Surgical Sling is intended for implantation to reinforce and support soft tissues where weakness exists, including but not limited to the following procedures: pubourethral support, prolapse repair (urethral, vaginal, rectal and colon), reconstruction of the pelvic floor, bladder support, sacrocolposuspension, reconstructive procedures and tissue repair. By providing pubourethral support, the FortaFlex™ Surgical Sling may be used for the treatment of urinary incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency. The device is intended for one-time use.

Device Description:
FortaFlex Surgical Sling consists of a multi-laminate sheet predominantly of Type I porcine collagen. The device is supplied in sheet form in sizes ranging from 2 cm x 5 cm to 12 cm x 36 cm in sterile double layer packaging.

Performance Data:
FortaFlex Surgical Sling was subjected to a panel of tests to assess biocompatibility, integrity, and performance. The device passed the requirements of all tests.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 3 0 2001

Mr. Patrick R. Bilbo
Director, New Products
Organogenesis, Inc.
150 Dan Road
Canton, Massachusetts 02021

Re: K011027
Trade Name: FortaFlex Surgical Sling
Regulation Number: 878.3300
Regulatory Class: II
Product Code: FTM
Dated: April 4, 2001
Received: April 5, 2001

Dear Mr. Bilbo:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

Applicant: Organogenesis Inc.

510(k) Number (if known): K011027

Device Name: FortaFlex™ Surgical Sling

Indications For Use:

FortaFlex™ Surgical Sling is intended for implantation to reinforce and support soft tissues where weakness exists, including but not limited to the following procedures: pubourethral support, prolapse repair (urethral, vaginal, rectal and colon), reconstruction of the pelvic floor, bladder support, sacrocolposuspension, reconstructive procedures and tissue repair. By providing pubourethral support, the FortaFlex™ Surgical Sling may be used for the treatment of urinary incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency.

The device is intended for one-time use.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011027

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)